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BOLESH J. SKUTNIK
CERAMOPTEC INDUSTRIES, INC.
515 SHAKER RD.
EAST LONGMEADOW, MA 01028

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

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Please find below and/or attached an Office communication concerning this application or proceeding.

DETAILED ACTION

The amendment dated 6-12-06 is acknowledged.

Claims included in the prosecution are 1-2, 5, 9, 11, 13-16 and 18-24.

In view of the amendment, the new matter rejection is withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-2, 5, 9, 11, 13-16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There are three figures in the specification and in the brief description of figures 2 and 3 apparently deal with the hair follicle reaction after a swellable composition is applied. However, nowhere in the specification one can find what swellable composition is applied. In fact, with regard to swellable composition, the specification only refers to some prior art and does not specifically disclose what compositions come under swellable compositions and what the gels, lotions, creams and others recited on page 9 of the specification contains. In fact, on page 9 of the specification states, "In one preferred embodiment, the substance is a form of microsphere or liposome. As disclosed in EP 03750520 and WO 98/48716,

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formulations containing specific size of ingredients (e.g. microspheres or liposomes) may target compounds to follicles". First of all, according to instant claim 18, the polymers are encapsulated in liposomes whereas according to applicant's statement above refers to the 'substance *is a* form of liposomes'. This means the liposome itself is a swellable composition. These two concepts are totally different. There is no guidance provided in the specification for either of the concepts for one of ordinary skill in the art to practice the invention without undue experimentation. Secondly there is no EP patent with the number recited. Thirdly, according to the English equivalent of the WO reference cited (US 6,287,549) the microspheres are made from even fatty substances (WO is one of the references which applicant recites as a guidance for the selection of swellable composition) such as fatty alcohols and triglycerides for the preparation of microspheres (col. 2, line 63 through col. 3, line 2). These are lipophilic compounds (water repellants) and it is unclear as to how they can swell within the follicles. According to col. 3, lines 3-5 of US 6,287,549, "vesicular microparticles may also be used as liposomes and, preferably, polymerized liposomes whether reverse or forward". This statement clearly implies that liposomes themselves are microparticles and not that the polymers are within the liposomes. In essence, instant specification does not provide adequate guidance to one of ordinary skill in the art as to which swellable compounds come under the definition of swellable compositions or how to use liposomes in practicing the invention without undue experimentation.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that swellable composition and polymers are noted on

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various pages. This argument is not persuasive since the issue here is the compositions are already in a swollen state and it is unclear as to how those polymers or compositions, which are in a swollen state, swell again inside the follicle. For example, as pointed out before, according to the specification, the compositions can be in the form of lotions, gels and creams meaning that there is some water in the composition. That means the swellable polymers are in an already swollen state before application. The specification does not disclose as to what is present in the gels, creams and lotions so as to enable one to apply the composition and then allow it to swell within the follicle. Instant specification does not provide adequate guidance for one of ordinary skill in the art to practice the invention without undue experimentation. The rejection is maintained.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-2, 5, 9-16 and 18-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from claim as to how the drug is applied in step d; that is, whether it is a solid, liquid etc. The specification does not provide guidance.

Applicant amends claim 2 to recite, "the method according to claim 1, wherein said swellable composition includes a compound/drug and wherein **thusly step d is effectively incorporated into step b**".

According to claim 9, 'the method according to claim 1, further comprising another step after step c: occluding said hair follicles'. This is confusing since according to claim 1, the compound/drug is applied in step d. Does that mean, the compound/drug is applied after occlusion?

It is unclear as to what applicant intends to convey by 'applying said compound/drug to said follicle area through said follicle lumen' in claim 1. Is the compound applied into the lumen or applied topically on the skin so that the compound penetrates the lumen? What is meant by 'for **increased application** of the compound? Does applicant mean increased amounts in the lumen? Step a already recites the simultaneous application of the compound and the swellable composition. Does that mean an additional amount of the compound is applied?

It is unclear as to what applicant intends to convey by 'compound/drug are molecules and their derivatives used in cosmetic/pharmaceutical applications'. A derivative of a compound will still be a compound and a derivative of a drug will still be a drug if it has the same properties of the drug; if not there is no point in administering a derivative, which is not a drug.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-2, 5, 9, 11, 13-16, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549).

WO teaches a method wherein a swellable polymeric particle or polymeric liposomal composition containing chromophores (phthalocyanins) is applied onto the skin. Since the composition in WO is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; a composition containing chromophores in a solvent is applied to the surface of the skin (instant step d). Since the same polymers are used they would swell the same way in instant method and the method in the prior art. The reference further teaches shaving the surface of the skin to be treated in order to make the hair follicles more accessible (see abstract, col. 2, line 17 through col. 3, line 50, col. 4, lines 8-12, col. 5, lines 62-67 and claims). WO does not provide specific examples showing the method using the liposomes (there are no examples in instant specification either). However, in view of the guidance provided by WO, it is deemed obvious to one of ordinary skill in the art to use liposomes with a reasonable expectation of success.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant argues that Sumian et al teaches (sic) ways to remove hair or improve permanency of such removal by a mechanical technique and this is not the invention claimed nor described in the present invention. According to applicant, the present invention is a method of enhancing drug penetration through unbroken stratum corneum without the need of needles, or other means to span this natural skin barrier. The compounds so transferred are then available in the patient's body to do whatever they are intended to do. Further according to applicant, the present invention provides alternatives to the use of needles, mere patches, topical cream or systemic methods to introduce the desired compound/drug into the patient and that is why the examiner is in error when he claims that the 'instant steps b and c are inherent in prior art. These arguments are not persuasive since the differences argued by applicant are not reflected in the claims. Claim 1 is drawn for method of enhancing compound/drug penetration into hair follicles on body areas and the prior art teaches the same using the same steps whether the subsequent use is for the hair removal or not. Applicant further argues that there is no requirement in 549 to have a swellable composition. This argument is not persuasive since whether it requires or not, the prior art uses the same composition and hence, it will swell just as in instant method.

8. Claims 1-2, 5, 9, 11, 13-16, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer (5,292,512) by itself or in combination with WO 98/48716 of record (English equivalent: US 6,287,549).

Schaefer teaches a method wherein a swellable polymeric particle composition containing various active agents is applied onto the skin for selective entry into follicles. The composition is applied to the skin with a gentle massage. Since the composition in Schaefer is the same as in instant application, instant steps, instant steps b and c are inherent in prior art; since the same polymers are used they would swell the same way in instant method and the method in the prior art (see abstract, col. 2, line 5 through col. 4, line 54, col. 5, line 1 through col. 8, line 35, Examples and claims). What is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. However, since the purpose of the method is to make the active agent in the composition to penetrate the follicles, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition. Furthermore, one of ordinary skill in the art would be motivated to shave the skin in view of WO teachings that shaving makes the hair follicles more accessible. Schaefer also does not teach the application of additional compound. However, in the absence of showing unexpected results, it is deemed to be within the skill of the art to apply additional active agent to the skin if an increased amount is needed to achieve the purpose. One of ordinary skill in the art would be motivated to apply additional compound with a reasonable expectation of success since WO 98 which is concerned with the penetration of an active agent in the hair follicles teaches that compound in a solvent could be applied.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant once again argues that in Schaefer the solvent is noted as the

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swelling agent for the microspheres themselves and that the composition is applied to the skin and enters the pilosebaceous orifices. This argument is not persuasive since Schaefer teaches on col. 7, lines 5-6 that the microspheres of 1-3 micrometers enter the follicles and there is nothing in Schaefer to indicate that the applied composition does not swell in the follicles. Schaefer teaches the composition in the form of gels just as in instant application (see specification on page 9, line 2 which recites gel). It should be noted that instant specification does not provide any information about the constituents of the gels. Instant specification does not specifically state what is present in the composition besides the swellable polymers. Applicant further argues that as contrasted with the present invention, Schaefer does not remove the hair and does not apply the swellable composition for the purpose of holding the opening the hair lumens for the infusion of chemicals therein. This argument is not found to be persuasive since as pointed out above, it is within the skill of the art to realize that the maximum penetration occurs when the hairs are shaved or cut before the application of the composition and WO is also suggestive of shaving the skin before application of the composition; since Schaefer applies the same composition, the opening of the hair lumens by the composition would be an inherent function of the composition itself. Applicant further argues that as particularly noted in Schaefer, claim 1, the microspheres are filled with at least one pharmaceutical product where as in the present invention, the swellable composition is applied to the hair follicle and then compound/drug is applied. This argument is not persuasive since instant amended claim step d indicates that the swellable composition includes a compound/drug.

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9. Claims 1-2, 5, 9, 11, 13-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/48716 of record (English equivalent: US 6,287,549) cited above, further in view of Li (5,914,126) and/or Nakamura, 1980.

The teachings of WO have been discussed above. What is also lacking in WO is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin or removing the hair and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and also from Nakamura. One of ordinary skill in the art would be motivated further to use liposomes, since liposomes are sustained release compositions and have been used in the art for the delivery of active agents as evident from Li.

Applicant's arguments have been fully considered, but are not persuasive. Applicant once again argues that from the text of Li, it is clear that the removal of hair was for the purpose of harvesting the skin for examination and also the band-aid was

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for the purpose of preventing removal and evaporation and neither of these features were the concern in the present invention. These arguments are not persuasive since WO teaches the accessibility of the hair follicles by shaving and the motivation to cover the skin need not be the same as applicants. Furthermore, Li uses the covering to immobilize the composition.

Applicant argues that Nakamura et al disclose the use of a tape having a composition thereon basically a batch with delayed absorption of a composition through normal stratum corneum, which is clearly different than the present invention. Applicant further argues that the removal of hair on the test mice was for improving the contact area for the tape on the composition on the skin. These arguments are not persuasive since as applicant himself recognizes that removal of hair improves the contact area even in instant case; that is, the presence of hair would result in less contact of the composition instant case just as in Nakamura.

10. Claims 1-2, 5, 9-16 and 18-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaefer cited above, further in view of Li (5,914,126) and/or Nakamura (1980).

The teachings of Schaefer have been discussed above. As pointed out above, what is lacking in Schaefer is the teaching of the removal of hair before application of the swellable composition. What is also lacking in Schaefer is the teaching of the occlusion of the area wherein the composition was applied with a cover.

Li while disclosing liposomal compositions for the delivery of the active agents to hair follicles teaches preshaving of the area to be treated and subsequent band-aid

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patch to immobilize the composition onto the skin to prevent evaporation (abstract, col. 41, line 62 through col. 42, line 2 and claims).

Nakamura while disclosing the anti-inflammatory activity of a topical glucocorticoid, fludroxycortide teaches that the depilation of the backs of the rats and then applying the tape containing fludroxycortide (abstract).

Preshaving of the skin and the occlusion of the area where the composition was applied would have been obvious to one of ordinary skill in the art since these are routinely practiced in the art as evident from Li and Nakamura.

Applicant's arguments with regard to Schaefer, Li and Nakamura have been addressed above. Applicant provides no other specific arguments regarding this rejection.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is (571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Woodward Michael can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK